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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,357	03/30/2004	Seiichi Saito	A8739	4105

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,357	SAITO, SEIICHI	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on May 10, 2006 in response to the Restriction Requirement of April 10, 2006 has been entered. Applicant's election of Group II, claims 16-32, as specifically drawn to a kit for diagnosing prostate cancer without traverse has been acknowledged. As such, the restriction requirement is therefore deemed to be proper and is made FINAL.

Claims 1-33 are currently pending.

Claims 1-15 and 33 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 16-32 are current under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 5/28/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said RM2 antibody" in claim 16. However, upon careful review of independent claim 16, there does not appear to be sufficient antecedent basis for this limitation in claim 16.

Claim 32 recites the limitation "said at least one antibody" in claim 28. However, upon careful review of dependent claims 28, 17 and independent claim 16, there does not appear to be sufficient antecedent basis for this limitation in claims 28, 17 and independent claim 16.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of moieties that bind to a RM2 antigen, having a specific epitope. However, the written description in this case only sets forth one species of moiety which specifically binds to the defined epitope of RM2, where said species is an antibody.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 9, paragraph 29) that examples of moieties that specifically react with RM2 are antibodies that specifically bind to the RM2 antigen. Thus, while the claims encompass a genus of molecules defined solely by their principal biological property, which is simply a wish to know the identity of any material with that biological property, the specification only appears to contemplate one species of moieties which specifically bind to RM2, wherein said species is an antibody. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative

number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of moieties that encompass the genus of moieties, which specifically bind to RM2, nor does it provide a description of structural features that are common to the genus. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of moieties which specifically bind to a RM2 antigen, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it

is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only one species of moiety which specifically binds to the defined epitope of RM2, where said species is an antibody, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(Note: The claim limitation "means for detecting the presence of said antigen by specific binding said moiety to said antigen" is being treated under 35 U.S.C. 112, sixth paragraph.)

Claims 16-27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (J. Biol. Chem. 1994; 269: 5644-5652, IDS) in view of Cordon-Cardo et al. (US 5,168,043, 1992).

Saito et al. teach a monoclonal antibody referred to an RM2 (abstract). Specifically, the reference teaches (Title) that the RM2 antibody specifically recognizes the common tetrasaccharide epitope NeuAcα2→3Galβ1→3(NeuAcα2→6)GalNAc found in disialosyl galactosyl globoside's (DSGG's) which is present in the instant claimed RM2 antigen having the epitope structure:

GalNAcβ1→4**(NeuAcα2→3)Galβ1→3(NeuAcα2→6) GalNAc**β1→3Galβ1→R

(*emphasis added to show common "core" epitope*).

Saito et al. further teach a means for detecting the presence of DSGG by specific binding of the RM2 antibody to said DSGG, wherein the detection was carried out immunohistologically using RM2 antibodies and FITC-conjugated goat antibodies (page 5445, 2nd column, *Immunohistochemical Staining of Tissue Sections and Reactivities of tumor cell line with mAbs RM1 and RM2*). Moreover, Saito et al. teach that DSGG's are strongly expressed in urogenital epithelia of blood group A and B nonsecretor individuals, wherein nonsecretor females have shown a much higher incidence of repetitive urogenital *Escherichia coli* infection than secretor females (page 5651, 1st column, last paragraph). As such, Saito et al. teach that MAb RM2 is a useful reagent for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection (page 5651, 2nd column).

Saito et al. do not explicitly teach a kit comprising the RM2 antibody.

Cordon-Cardo et al. teach a diagnostic kit of use in determining whether an individual is a secretor which comprises a monoclonal antibody, which can be used for determining whether a female is susceptible to a urogenital infection comprising detecting the presence of an Le^a or Le^b antigen with a monoclonal antibody specific for said Le^a or Le^b antigen (column 3, line 65 to column 4, line 15 and column 4, lines 40-52). With regards to the kits, the patent teaches that the kits will comprise monoclonal antibodies separately packed which will allow one to perform sequential testing (column 18, lines 43-49).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the antibody as taught by Saito et al. in the form of a kit for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting

susceptibility to this type of infection in view of Cordon-Cardo et al. teachings that kits comprising monoclonal antibodies allows one to perform sequential testing. One would have been motivated to do so because as taught by Saito et al. MAb RM2 is a useful reagent for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by packaging the antibody as taught by Saito et al. in the form of a kit, one would achieve a kit which would allow one to perform sequential testing for the evaluating the susceptibility of an individual to an urogenital infection.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (J. Biol. Chem. 1994; 269: 5644-5652, IDS) in view of Cordon-Cardo et al. (US 5,168,043, 1992) in further view of Tannock, I.F. and Hill, R.P (The Basic Science of Oncology, 3rd Ed., New York: McGraw-Hill, 1998).

Saito et al. in view of Cordon-Cardo teach, as applied to claims 16-27 and 30-31, a kit comprising a monoclonal antibody referred to an RM2, which specifically recognizes the common tetrasaccharide epitope NeuAcα2→3Galβ1→3(NeuAcα2→6)GalNAc found in disialosyl galactosyl globoside (DSGG) which is present in the instant claimed RM2 antigen having the epitope structure:

GalNAcβ1→4**(NeuAcα2→3)Galβ1→3(NeuAcα2→6) GalNAc**β1→3Galβ1→R

(*emphasis added to show common "core" epitope*).

Saito et al. further teach a means for detecting the presence of DSGG by specific binding of the RM2 antibody to said DSGG, wherein the detection was carried out immunohistologically using RM2 antibodies and FITC-conjugated goat antibodies (page 5445, 2nd column, *Immunohistochemical Staining of Tissue Sections and Reactivities of tumor cell line with mAbs RM1 and RM2*). Moreover, Saito et al. teach that DSGG are strongly expressed in urogenital epithelia of blood group A and B nonsecretor individuals, wherein nonsecretor females have shown a much higher incidence of repetitive urogenital *Escherichia coli* infection than secretor females (page 5651, 1st column, last paragraph). As such, Saito et al. teach that MAb RM2 is a useful reagent for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection (page 5651, 2nd column).

Saito et al. in view of Cordon-Cardo do not explicitly teach that the means of detecting was carried out via sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) followed by Western blot analysis.

Tannock and Hill teach methods of genetic analysis (page 26, Chapter 3). Specifically, the textbook teaches that an analogous procedure to Northern Blot analysis is Western Blot analysis which characterize proteins and involves separation by electrophoresis, immobilization of the proteins on nitrocellulose and incubation with a solution containing a specific antibody to said protein such that the antibody will only bind to the region of the filter containing the protein.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunohistochemical means for detecting the DSGG antigen as taught by Siato et al for SDS PAGE followed by Western Blotting as taught by Tannock and Hill. One would have been motivated to do so because as evidenced by the Tannock and Hill text book, those of skill in the art recognize that immunohistological analysis and SDS-PAGE followed by Western Blot analysis performs identical functions in substantially the same way and produces substantially the same results. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by substituting SDS-PAGE followed by Western Blot analysis, one would achieve an equivalent means for determining the presence of an antigen by specific binding of an antibody to said antigen.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
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BF
July 11, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER